

## **Exhibit A**

EXECUTION VERSION

## MASTER MANUFACTURING SUPPLY AGREEMENT

This **Master Manufacturing Supply Agreement** (this “**Agreement**”) is hereby entered into as of November \_\_, 2020 (the “**Effective Date**”) by and arch between CoreRx, Inc., a Florida corporation, with offices located at 14205 Myerlake Circle, Clearwater FL 33760 and its Affiliates, (collectively, “**CoreRx**”) and Bionpharma Inc., (“**Bion**”), a Delaware corporation, having its principal place of business at 600 Alexander Road, Suite 2-4B, Princeton, NJ 08540 (each, a “**Party**” and collectively, the “**Parties**”).

### Background

Bion is in the business of commercializing various generic pharmaceutical products. CoreRx has experience in manufacture and supply of Products.

**NOW THEREFORE**, in consideration of the mutual promises, covenants and agreements hereinafter set forth and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Bion and CoreRx hereby agree as follows:

## ARTICLE 1. DEFINITIONS

**1.1 Defined Terms.** Capitalized terms used in this Agreement and not otherwise defined herein shall have the meaning set forth below:

“**Affiliate(s)**” means as to a Party, any party which controls, is controlled by, or is under common control with such Party. For purposes of the foregoing definition, the term “control” (including with correlative meaning, the terms “controlling”, “controlled by”, and “under common control with”) as used with respect to any applicable party, shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such party, whether through ownership of equity, securities, or partnership interest or by contract, or otherwise. Ownership of more than fifty percent (50%) of the securities or other ownership interests representing the equity, the voting stock or general partnership interest in an entity, or greater than fifty percent (50%) interest in the income of such corporation or other business entity shall, without limitation, be deemed to be control for purpose of this definition.

“**ANDA**” means an Abbreviated New Drug Application prepared in conformance with applicable FDA regulations for filing with the FDA for marketing authorization of a given Product.

“**Agency**” means any applicable local, national or supranational government regulatory authority involved in granting approvals and/or exercising authority with respect to the manufacture of a pharmaceutical product in the Territory, including in the FDA.

“**API**” means the active pharmaceutical ingredient and related substance or substance combination used in manufacturing the Product.

“**Applicable Laws**” means all laws, rules, regulations and guidelines of any Governmental Authority with jurisdiction over the development, manufacturing, exportation, importation, promotion, marketing, sale or distribution of the Product and/or the performance of a Party’s obligations under this Agreement, to the extent applicable and relevant, and including specifically, but without limitation, the FD&C Act, all cGMP and current Good Clinical Practices or similar standards or guidelines of the FDA and including trade association guidelines, where applicable, as well as U.S. export control laws and the U.S. Foreign Corrupt Practices Act.

**“Batch”** means the Product that results from a single Manufacturing process, inclusive of Material.

**“Bion Intellectual Property”** means Know-How, including Bion Improvements, that is owned or Controlled by Bion or its Affiliates during the term of this Agreement and that is necessary for or directly related to the Manufacture, use, sale, offering for sale or importing of the Products, including any tangible materials that are provided by Bion to CoreRx for use in the conduct of any Program. The term Bion Intellectual Property does not include any Know-How, which is, as of the Effective Date or later becomes, generally available to the public, excluding Bion Confidential Information or Know-How owned or Controlled by Bion that is publicly disclosed by a Third Party without the consent of Bion, and Know-How included in Bion Patent Rights.

**“Bion Patent Rights”** means those Patent Rights that Cover Bion Intellectual Property and are Controlled by Bion at any time during the term of this Agreement.

**“Business Day”** means any day other than a Saturday, a Sunday, or a national holiday in the United States.

**“Business Failure”** means (i) an actual failure of CoreRx (or any of its Affiliates) to pay its (or their respective) employees or vendors, or to meet its (or their respective) other financial obligations, (ii) a determination by Bion (in its reasonable belief) that CoreRx (or any of its Affiliates) may be unable to pay its (or their respective) employees or vendors, or to meet its (or their respective) other financial obligations, and CoreRx’s failure to provide assurances (within thirty (30) days after written notice thereof by Bion) reasonably satisfactory to Bion that CoreRx (and its Affiliates) will be able to make such payments and meet such obligations, (iii) CoreRx (or any of its Affiliates) becoming the subject of any voluntary or involuntary receivership proceeding, bankruptcy, insolvency, liquidation, or assignment for the benefit of creditors, (iv) a determination by Bion (in its reasonable belief) that CoreRx (or any of its Affiliates) may become the subject of any voluntary or involuntary receivership proceeding, bankruptcy, insolvency, liquidation, or assignment for the benefit of creditors, and CoreRx’s failure to provide assurances (within thirty (30) days after written notice thereof by Bion) reasonably satisfactory to Bion that any such proceeding or action will not occur, or (v) a determination by Bion (in its reasonable belief) that CoreRx may be unable to satisfy any of its obligations under this Agreement (which may be based on actual or perceived risks, including performance risks, ethical risks, financial solvency risks or other risks); in each case of any of the foregoing, even if as a result of Force Majeure.

**“cGMP”** means current good manufacturing practices as set forth in 21 C.F.R. §§ 210 and 211, or any Applicable Law, similar regulations, guides, guidances or directives, as amended from time to time.

**“Commercialize” or “Commercialization”** means the commercial exploitation of a Product through (i) manufacturing and selling the Product, (ii) assigning or licensing some or all the commercial rights to the Product to third parties, (iii) entering into a joint venture, partnership or other business arrangement regarding the manufacture, marketing and/or sale of the Product, or (iv) some other agreement or arrangement to produce revenue from the Product.

**“Commercially Reasonable Efforts”** means, with respect to each Party, the efforts and commitment of resources in accordance with such Party’s reasonable business, legal, medical, and scientific judgment that are consistent with the efforts and resources such Party uses for other Product owned by it or to which it has exclusive rights, which are of similar market potential and at a similar stage in their life cycle, taking into account the competitiveness of the marketplace, the regulatory structure involved, the profitability of the applicable Product and other relevant factors, including technical, legal, scientific, medical, sales performance, and/or marketing factors. The term “Commercially Reasonable” shall have correlative meaning.

**“Confidential Information”** means all non-public information of any kind whatsoever (including without limitation, data, materials, compilations, formulae, models, patent disclosures, procedures, processes, projections, protocols, results of experimentation and testing, specifications, strategies,

techniques and all non-public Intellectual Property and Know-How ), and all tangible and intangible embodiments thereof of any kind whatsoever (including without limitation, materials, samples, apparatus, compositions, documents, drawings, machinery, patent applications, records and reports), which are disclosed by either party to the other Party including any and all copies, replication or embodiments thereof. The terms, subject matter and substance of this Agreement shall be deemed the Confidential Information of both Parties. Confidential Information shall not include information which: (a) is known to the receiving Party, as evidenced by the receiving Party's prior written records, before receipt thereof under this Agreement; (b) is disclosed to the receiving Party by a third person who is under no obligation of confidentiality to the disclosing Party hereunder with respect to such information and who otherwise has a right to make such disclosure; (c) is or becomes generally known in the public domain through no fault of the receiving Party; or (d) is independently developed by the receiving Party, as evidenced by the receiving Party's written records, without access to such information

**“Control” or “Controlled”** means, with respect to any information, intellectual property right or Regulatory Approval, possession by a party of the ability (whether by ownership, license or otherwise) to grant access, rights, title, possession, a license or a sublicense, as applicable, to such intellectual property right without violating the terms of any Third Party agreement, court order, or other arrangement or legal obligation.

**“CoreRx Equipment”** means all equipment and machinery used to (or otherwise necessary for), directly or indirectly, Manufacture Product,

**“CoreRx Intellectual Property”** means Know-How that is owned or Controlled by CoreRx or its Affiliates during the term of this Agreement and that is related to the Manufacture, use, sale, offering for sale or importing of the Products, including any tangible materials that are provided by CoreRx to CoreRx for use in the conduct of any Program. The term CoreRx Intellectual Property does not include any Know-How, which is, as of the Effective Date or later becomes, generally available to the public, excluding CoreRx Confidential Information or Know-How owned or Controlled by CoreRx that is publicly disclosed by a Third Party without the consent of CoreRx, and Know-How included in CoreRx Patent Rights.

**“CoreRx Patent Rights”** means those Patent Rights that Cover CoreRx Intellectual Property and are Controlled by CoreRx at any time during the term of this Agreement.

**“Cover”** means (a) with respect to a granted patent, a Valid Claim thereof would be infringed in the absence of a right, authorization, consent or license with respect to such claimed subject matter, or (b) with respect to a patent application that has not been granted, a Valid Claim thereof, that if granted, would be infringed in the absence of a right, authorization, consent or license with respect to such claimed subject matter.

**“Delivery” or “Deliver” or “Delivered”** means CoreRx's delivery of Product in accordance with the Delivery Terms.

**“Delivery Address”** means, with respect to a given order of Product, the address where the quantities of Product under such order are to be shipped, as set forth in the applicable order.

**“Delivery Date”** means the date by which Bion shall take delivery of Product as set forth in a Firm Order.

**“Delivery Terms”** means, with respect to a given Product, the delivery terms (based on Incoterms 2010) for the delivery of such Product. Unless otherwise set forth in the Addendum for a given Product, the “Delivery Terms” for each Product shall be FCA the Delivery Address.

**“Dollar”** means the United States dollar.

**“DMF”** means the drug master file as described in 21 C.F.R. §314.420 containing detailed information concerning the synthesis, manufacture, analysis and stability of the API as required for the manufacture, importation, marketing and sale of the Product in the Territory.

**“Drug Product”** means a drug product as defined in 21 C.F.R. §314.3 for administration to human subjects.

**“Facility”** means with respect to a given Product, (a) CoreRx’s M-1 facility located at 14205 Myerlake Circle, Clearwater, FL 33760 and/or M-2 facility located at 5777 Myerlake Circle, Clearwater FL 33760, and/or M-3 facility located at 5733 Myerlake Circle, Clearwater, FL 33760, as well as (b) such other facility where such Product may be Manufactured as approved by Bion in writing pursuant to Section 3.7.

**“FDA”** means the United States Food and Drug Administration or any successor agency thereto.

**“FD&C Act”** means the Food, Drug & Cosmetic Act of 1938 and applicable regulations promulgated thereunder, as amended from time to time.

**“Firm Order”** means a purchase order for a given Product issued by Bion (and/or its Affiliate, as applicable) under this Agreement and the relevant Addendum. Each Firm Order shall specify the quantity of Product ordered, the pack size, the required Delivery Date, and the Delivery Address (as well as any specific shipping instructions, if applicable), in each instance in accordance with this Agreement.

**“First Commercial Sale”** means the means the first transfer for value in an arms-length transaction to a Third Party distributor, agent or end user in a country within the Territory after obtaining all Regulatory Approvals necessary for such transfer in such country.

**“GAAP”** means United States Generally Accepted Accounting Principles in effect from time to time, consistently applied.

**“Governmental Authority”** means any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (i) any government of any country, or (ii) a federal, state, province, county, city or other political, administrative or regulatory subdivision thereof.

**“Know-How”** means, with respect to a given Product, proprietary information concerning: manufacturing protocols and methods, Product formulations, product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing information, engineering and other manuals and drawings, standard operating procedures, flow diagrams, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, safety, quality assurance, preclinical data, quality control and clinical data, technical information, and research records.

**“Label,” “Labeled” or “Labeling”** shall refer to such labels and other written, printed or graphic matter, (i) upon a Product or any container or wrapper utilized with the Product, or (ii) accompanying a Product, including without limitation, package inserts.

**“Latent Defect”** means any deficiency (including any Product that fails to meet the representations, warranties or other quality requirements set forth in this Agreement) that was not discovered by Bion upon a reasonable inspection of the Product (based on physical inspection, identity test and review of the certificate of analysis).

**“Losses”** means any and all liabilities, losses, fines (including criminal, administrative and civil fines), costs, damages or expenses, including reasonable attorneys’ fees.

**“Manufacture” or “Manufacturing” or “Manufactured”** means, with respect to a given Product, all operations performed by CoreRx for the manufacture and commercial supply of such Product hereunder, including, as applicable, receipt (including testing) and storage of Materials, production, formulation, filling, visual inspection, packaging, labeling, handling, warehousing, quality control testing (including in-process, initial release and stability testing), release, as applicable, and shipping of Product, and also including such activities as may be specified in the ANDA approval and master batch records

**“Materials”** means all raw materials, including API, components (including packaging materials), and

other potential product-contacting items necessary for, or otherwise used in, the Manufacture of Product hereunder, as applicable.

**“Minimum Remaining Percentage”** means, with respect to a given Product, the minimum percentage of the maximum shelf-life for such Product that is required to be remaining at the time of Delivery of such Product hereunder, which shall in all cases be ninety (90%).

**“Orange Book”** means the *Approved Drug Product with Therapeutic Equivalence Evaluations* published by the FDA, as amended.

**“Overhead”** means all customary and usual operating expenses directly related to the Product incurred by and in support of the particular manufacturing cost centers, purchasing department and quality assurance operations, related to the Product (including labor, related payroll taxes and employee benefits), depreciation, general taxes, rent, repairs and maintenance, supplies, utilities and factory administrative expense.

**“Packaging”** means all primary containers, including bottles, cartons, shipping cases or any other like matter used in packaging or accompanying a Product.

**“Patent Rights”** means patents and patent applications, divisionals, continuations, continuations-in-part, reissues, extensions, supplementary protection certificates and foreign counterparts thereof.

**“Person”** means an individual, corporation, partnership, limited liability company, firm, association, joint venture, estate, trust, governmental or administrative body or agency, or any other entity.

**“Pharmacovigilance Expenses”** means expenses related to managing and administering to safety reporting system and its related activities for the sale of pharmaceutical products in the Territory as required by Applicable Law.

**“Proceedings”** means, without limitation, governmental, judicial, administrative or adversarial proceedings (public or private), litigation, suits, arbitration, disputes, claims, causes of action or investigations.

**“Product”** or **“Products”** means the particular Products to be supplied hereunder. Product supplied hereunder in liquid, powder or semi-solid form will be provided in final finished packaged form ready for marketing, distribution and sale or other use and Product supplied hereunder in capsule or tablet form will be provided in bulk format. For clarity, unless the context otherwise requires, references to “Product” in this Agreement shall be construed to refer to each given Product hereunder (and thus understood to mean a given Product on a “Product-by-Product” basis); provided, that to the extent the term “Product” is used more than one time in a given provision herein, the first such reference shall be understood to mean “a given Product” and each successive reference shall be understood to mean “such Product”.

**“Quality Agreement”** means that certain quality agreement to be executed by the Parties (or their respective Affiliates) setting out the roles and responsibilities related to the Manufacturing of Product, as such agreement may be amended from time to time by the Parties.

**“Reference Product”** means all approved strengths and dosage forms that are approved for sale of the reference listed brand Drug Product, listed in the Orange Book or other relevant database of the FDA.

**“Regulatory Approval”** means the applicable approvals necessary to make Product, including applications submitted to the FDA, and all applicable product and/or establishment licenses, registrations, permits or other authorizations as may be necessary in connection with the applicable Product, and which are necessary for the commercial manufacture, commercialization, use, storage, importation, transport, promotion, pricing, distribution or sale of such Product in the Territory, including, without limitation, an ANDA

**“SDE Agreement”** means a safety data exchange agreement to be entered into by the Parties which addresses pharmacovigilance matters.



**“Specifications”** means, with respect to a given Product, the then most current specifications for both the API and the Product established by CoreRx and approved by Bion, as set forth in any applicable application for Regulatory Approval, or prior to the application, as embodied in applicable documents leading up to such application (e.g., in connection with a bioequivalence study), or as may be superseded in the future by an applicable Regulatory Approval for such a Product, including (as applicable) any supplements or amendments thereof and statements of pharmaceutical manufacturing, filling, storage and quality control procedures, submission batch specifications, and Labeling and Packaging specifications (as such may be revised from time to time in accordance with Applicable Laws) together with any additional specifications that may be agreed to between the Parties.

**“Territory”** means the United States, its territories and possessions including, without limitation, Puerto Rico and the District of Columbia.

**“Therapeutic Equivalent”** means a Drug Product that is therapeutically equivalent (as such term is defined in the Orange Book) to the Reference Product.

**“Third Party”** or **“Third Parties”** means any Person or entity other than a Party or its Affiliates.

**“Third Party Claim”** means any claim, demand, proceeding, action or cause of action by a Third Party.

**“Transfer Price”** means the price agreed by the Parties for a Product as specified in Attachment 2 hereof, and mutually amended from time to time by electronic email or other written format.

**“Validation”** or **“Validating”** or **“Validated”** means documented evidence that provides a high degree of assurance that the Manufacturing process controls are adequate to consistently produce a Product, in accordance with cGMPs and Bion Intellectual Property, and that meets the Product Specifications.

**“Valid Claim”** means a claim of (a) a granted patent which has not been disclaimed, abandoned or surrendered or declared invalid or unenforceable in a final, unappealable or unappealed decision of a judicial or administrative court, government agency or patent office of appropriate jurisdiction, or (b) a patent application which has not been formally terminated or abandoned, without right of appeal, without issuance of a patent, or has not been in active prosecution for more than five (5) years without issuance of a patent.

**“Violation”** means that either CoreRx, or any of its officers, directors, or subcontractors has been: (a) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General website, including 42 U.S.C. 1320a-7(a) (<https://oig.hhs.gov/exclusions/authorities.asp>); (b) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (<https://oig.hhs.gov/exclusions/index.asp>) on said website or the U.S. General Services Administration’s list of Parties Excluded from Federal Programs (<http://www.sam.gov>); or (c) listed by any US Federal agency as being suspended, debarred, excluded, or otherwise ineligible to participate in Federal procurement or non-Procurement programs, including under 21 U.S.C. 335a ([http://www.fda.gov/ora/compliance\\_ref/debar/](http://www.fda.gov/ora/compliance_ref/debar/)) (each of (a), (b) and (c) collectively the **“Exclusions Lists”**).

**“Waste”** means any waste material, pollutant, contaminant, toxin, carcinogen, biohazard, radioactive or hazardous gaseous, liquid or solid material of any kind or any other waste that may or could pose a hazard to the environment or human health or safety, including any routine process waste or any by-product, arising from Manufacture of Product, including petroleum, petroleum hydrocarbons, petroleum products or petroleum by-products, radioactive materials, asbestos or asbestos-containing materials, gasoline, diesel fuel, pesticides, radon, urea formaldehyde, mold, lead or lead-containing materials, polychlorinated biphenyls and any other chemicals, materials, substances or wastes in any amount or concentration which are now or hereafter become defined as or included in the definition of

“hazardous substances”, “hazardous materials”, “hazardous wastes”, “extremely hazardous wastes”, “restricted hazardous wastes”, “toxic substances”, “toxic pollutants”, “pollutants”, “regulated substances”, “solid wastes”, or “contaminants” or words of similar import under Applicable Laws.

**1.2 Other Defined Terms.** The following terms shall have the meanings set forth in the section appearing opposite such term:

“Agreement”	Preamble
“Approved Manufacturer”	Section 5.14
“Bion”	Preamble
“Bion Improvements”	Section 10.4
“Bion Parties”	Section 13.2
“Continuous Improvement Program”	Section 6.4
“CoreRx”	Preamble
“CoreRx Parties”	Section 13.1
“Data Set”	Section 7.14
“Deficiency”	Section 12.3
“Dispute”	Section 16.7
“Effective Date”	Preamble
“Force Majeure Event”	Section 16.9
“Offer Notice”	Section 15.1
“Party(ies)”	Preamble
“Supply Interruption”	Section 5.11
“Taxes”	Section 6.8.

## **ARTICLE 2. MASTER AGREEMENT; SCOPE OF WORK; DEVELOPMENT**

**2.1 Master Agreement.** This Agreement establishes the general terms and conditions applicable to CoreRx’s Manufacture and supply of the Product hereunder and the performance of activities under this Agreement with respect to the Product hereunder.

## **ARTICLE 3. FACILITY AND EQUIPMENT**

**3.1 Implementation.** CoreRx will design the layout of the portion of the Facility used to Manufacture Products and equip the production line(s) for the Products located at the Facility in accordance with a jointly agreed plan and schedule as may be necessary to deliver a production line that meets the specifications for the production line and the Facility that are established by mutual agreement of the Parties. CoreRx shall not change the specifications for the production line specifications without consulting Bion. On not less than seven days’ notice to CoreRx, Bion will have the right to inspect the progress of work at the Facility relating to the performance of this Agreement at all reasonable times during the implementation process and to confer with CoreRx to confirm compliance with the agreed specifications for the production line(s) for the Products, and Bion will be consulted concerning any matters that could cause a delay in completion of the production line(s) at the Facility. Bion and CoreRx will, from time to time during the implementation process, confer regarding the quality standards for the layout of the production line operations.

**3.2 Maintenance and Operation.** CoreRx agrees, at its own cost, to maintain and operate the Facility, and the CoreRx Equipment used directly or indirectly to Manufacture Product, in an acceptable state of repair and operating efficiency, and in accordance with Applicable Law (including cGMPs) all applicable Bion Intellectual Property and all applicable Agency requirements.

**3.3 Qualification and Validation.** CoreRx, at its cost, shall be responsible for Validating the CoreRx Equipment (including conducting installation, operational and performance qualification), production, cleaning, packaging, process and any other appropriate steps performed at the Facility in accordance with the Bion Intellectual Property and as required by, and in accordance with, the Applicable Laws (including cGMPs); Validation procedures used by CoreRx immediately prior to the Effective Date may be used; provided that such procedures (i) are found to be acceptable to Bion, (ii)



meet applicable regulatory requirements and (iii) are found acceptable by Agency inspectors, if applicable. If Bion or any Agency finds CoreRx's Validation procedures to be unacceptable, then all Validation must be repeated to meet the criteria given in the Bion Intellectual Property and all applicable regulatory requirements and guidelines and to receive all Agency and Bion approvals. Notwithstanding the foregoing, if Bion reasonably finds, or any Agency finds, CoreRx's validation or qualification procedures to be unacceptable, then all validation or qualification must be repeated to meet the criteria given in the cGMPs and Bion Intellectual Property and, as applicable, to the satisfaction of the Agency or Bion, as applicable. CoreRx shall ensure the cleanliness of the equipment, using a cleaning validation procedure that complies with FDA requirements, prior to Manufacturing Product.

**3.4 Equipment Problem.** CoreRx agrees that in the event that either CoreRx Equipment is inoperable and such inoperation is expected to result in a delay of supply of Product to Bion, CoreRx shall notify Bion immediately in writing of such problem and CoreRx shall work to expeditiously rectify any such problems. CoreRx will inform Bion immediately if Delivery of any Firm Order will be delayed. With respect to all CoreRx Equipment, CoreRx shall be responsible for the costs of all maintenance and repairs, including all spare parts.

### **3.5 Changes and Change Control.**

3.5.1 Notwithstanding anything herein to the contrary or in the Quality Agreement, except as otherwise agreed to by Bion in writing or as may be required to comply with the Applicable Laws (including cGMPs), CoreRx shall not amend, change, or supplement any of the following without Bion's prior written consent: (1) the Product Specifications; (2) the Materials; (3) the specifications for Materials that have regulatory impact (e.g., specification is listed in the regulatory filing) or the potential for quality impact on the Products; (4) the source of Materials that have regulatory impact (e.g., supplier is listed in the regulatory filing) or the potential for quality impact on the Products; (5) the Bion Intellectual Property or CoreRx Intellectual Property; (6) the equipment and machinery, other than in-kind replacements, used in the Manufacture of Product that have a direct impact on the quality of the Product; (7) the test methods used in connection with the Manufacturing of Product that have regulatory impact (e.g., method is listed in the regulatory filing) or the potential for quality impact on the Products; (8) the process for Manufacturing Product or Materials; (9) the cleaning process or procedures used at any time on the equipment and machinery used in the Manufacture of Products; and/or (10) any DMF for a Product.

3.5.2 Any change in any of the foregoing shall, in each instance, comply with the Applicable Laws (including cGMPs) and shall be made in accordance with the Quality Agreement. In the event that CoreRx is required to change any of the foregoing in order to comply with the Applicable Laws (including cGMPs) or such change is otherwise agreed to by Bion in writing, CoreRx shall: (x) immediately notify Bion of such change and use commercially reasonable efforts to implement such change as soon as reasonably practicable; (y) be responsible, at its expense, for ensuring that all Product Manufactured following such change meets the Product Specifications and the Product quality and yields achieved during the validation batches; and (z) provide Bion with all information with respect to the Manufacture of the Product in connection with such change needed to amend any regulatory filings (including ANDAs) maintained with respect to the subject Product. To the extent permitted by Applicable Laws, CoreRx shall continue to supply Bion with Product approved under any applicable existing DMF and/or Bion's existing regulatory filings (including ANDAs), as applicable, for the subject Product until such time as the Product Manufactured following such change is permitted under the amended regulatory filings therefor. In the event that CoreRx intends to change any of the foregoing, Bion shall work in a timely fashion to provide any required response to CoreRx.

3.5.3 Prior to implementing any such change, the Parties shall agree on the reasonable costs thereof; provided that CoreRx shall use commercially reasonable efforts to mitigate the costs thereof. Notwithstanding the foregoing, (i) if the change is required by Applicable Laws and such required change benefits the Manufacture of the Product, as well as the manufacture of other products by CoreRx at the Facility, then Bion shall be responsible for reimbursing CoreRx for a proportionate share of the

costs (based on the relative benefits to the Products hereunder and the benefits to such other CoreRx products taking into account the remaining duration of the Term), and in the event that the Parties disagree as to such costs or such proportionate share, the matter shall be resolved in accordance with Section 16.7 (and in making its determination the Parties shall take into account the remaining duration of the Term) and (ii) in all other cases, CoreRx shall bear all costs of such change.

**3.6 Discretionary Changes.** In the event that either Party desires to propose discretionary changes (i.e., changes which are not required by cGMPs or other Applicable Laws) during the Term to the Product Specifications or to the Manufacturing process (in each case, which discretionary changes would otherwise require consent as set forth in Section 3.6.1), the Parties shall discuss such discretionary changes and any Manufacturing issues identified by either Party in connection with implementing such change. In all cases, such discretionary changes shall be made in accordance with any change control procedures in the Quality Agreement to the extent applicable. The provisions of Sections 3.6.2 and 3.6.3 shall apply with respect to implementing any such discretionary change. Notwithstanding the foregoing, in all cases, the Product Specifications may be amended or supplemented from time to time by Bion upon written notice to CoreRx in accordance with any change control procedures in the Quality Agreement.

**3.7 Manufacturing at Facility.** CoreRx shall Manufacture all Product supplied hereunder at the Facility. Manufacturing of Product may not be relocated from the Facility without Bion's prior written consent (it its sole discretion). Any such relocation of the Manufacturing of a given Product shall comply with the Applicable Laws (including cGMPs) and shall be made in accordance with Sections 3.6.2 and 3.6.3, and the Quality Agreement, to the extent applicable. Without limiting the foregoing, in the event that CoreRx desires to relocate the Manufacturing of any Product, in connection with such relocation, the Parties shall discuss any amendments to this Agreement as reasonably requested by Bion or the CoreRx (as the case may be), including with respect to (i) the Delivery Terms, (ii) provisions related to transfer of title, in each case, to take into account the relocation of such activities, and (iii) the procedures to be followed to secure any Regulatory Approvals required by in connection with such relocation. CoreRx shall be responsible for the costs of any relocation and any Product cost increase in connection with such relocation.

**3.9 Manufacture of Product.** For the avoidance of doubt, each change referred to in Section 3.5 or Section 3.6 or Section 3.7 shall be agreed to by the Parties (to the extent such agreement is required pursuant to Section 3.5 or Section 3.6 or Section 3.7), as applicable, including the implementation date of any such change, only as it applies to Manufacturing of Product.

**3.10 Storage.** CoreRx shall, in accordance with the Applicable Laws (including cGMPs), Bion Intellectual Property, and Product Specifications, maintain adequate storage accommodations for all of the Materials, Product and any other materials or products reasonably requested by Bion. CoreRx shall notify Bion immediately whenever the inventories of Materials become insufficient to Manufacture the Product to meet the Delivery Date(s). Products that have been quality control released by CoreRx shall be stored by CoreRx in separate segregated area until Delivered.

**3.11 Waste.** In connection with the Manufacture of Product hereunder, CoreRx shall be solely responsible for maintaining safety procedures in connection with the Manufacture of Product and for the generation, treatment, storage and/or disposal of Waste relating thereto, all of which shall comply with all Applicable Laws, including all applicable environmental and occupational safety and health requirements in the jurisdiction of the Facility. At the request of Bion, CoreRx shall provide a Certificate of Destruction to Bion upon completion of disposal of any Waste.

#### ARTICLE 4. MATERIALS

**4.1 Materials.** CoreRx shall be responsible for procuring all Materials in adequate quantities to Manufacture each Product. CoreRx shall purchase adequate quantities of the Materials. Bion and CoreRx shall be responsible for negotiating the price for such Materials. For clarity, the Transfer Price already takes into account the costs of Materials, and Bion shall not be liable to CoreRx for any

increases in the cost of such Materials except as provided in Section 6.2.

**4.2 API Supply.** With respect to API for each Product, CoreRx shall take actions to ensure that all API supplied by the API manufacturer is manufactured in accordance with cGMP and all Applicable Laws and that the manufacturer has a successful history in satisfying all FDA requirement at the facility supplying the API; that the API is consistent with the applicable Product Specifications and Regulatory Approval (or associated application prior to approval) and is in compliance with applicable compendial (e.g. United States pharmacopeia) specifications for such API; and that the manufacturer of the API provides letters of authorization necessary or useful for the FDA to access the DMF for the API to the extent necessary or useful to support Bion's efforts to obtain and maintain Regulatory Approvals for the Product in the Territory. The Parties shall also take steps to identify an alternate source for API no event later than twelve (12) months after the filing of Regulatory Approval for the Product in the Territory.

## **ARTICLE 5. PRODUCT ORDERS; DELIVERY**

**5.1 Manufacture and Supply of Product.** Subject to the receipt of marketing approval, Bion hereby appoints CoreRx to Manufacture Product at the Facility. CoreRx accepts such appointment to Manufacture Product and to do such other acts as are herein authorized. Subject to the terms and conditions of this Agreement, CoreRx shall Manufacture and supply to Bion, and Bion shall purchase from CoreRx, Product that is ordered by Bion pursuant to Firm Orders submitted in accordance with this Agreement. Product shall be Manufactured and supplied by CoreRx in accordance with this Agreement and the relevant Firm Order. Subject to the terms and conditions of this Agreement, each Firm Order shall be considered a separate Firm Order and shall be valid and binding upon its submission by Bion in accordance with this Agreement. Bion shall purchase the Products exclusively from Core Rx and CoreRx shall Manufacture and supply the Products exclusively for Bion and not for any Third Party. Product Manufactured under this Agreement pursuant to Firm Orders shall be the exclusive property of Bion.

**5.2 Monthly Forecast.** During the Term of this Agreement, Bion shall provide to CoreRx, on a monthly basis, a non-binding rolling forecast of its Product requirements for the next twelve (12) months (or for the remainder of the Term, whichever is less). The forecasts for the first three (3) months of any 12-month period shall represent binding purchase obligations of Bion with respect to the Products.

**5.3 Firm Orders.** Bion shall place Firm Orders for its requirements of each Product at least ninety (90) days before the requested Delivery Date unless an alternative lead time for a given Product is otherwise agreed, in which event Bion shall place such Firm Order no later than the number of days equal to such lead time. Firm Orders will be made on such form of purchase order or document as Bion may specify from time to time in writing; provided that the terms and conditions of this Agreement shall be controlling over any terms and conditions included in any Firm Order. Any term or condition of such Firm Order that is different from or contrary to the terms and conditions of this Agreement shall be void, unless otherwise agreed between the Parties in writing.

**5.4 Delivery Against Firm Orders.** CoreRx will acknowledge all Firm Orders within five (5) days following receipt of same and will deliver all orders within ninety (90) days following the date such Firm Order is received. CoreRx will accept all Firm Orders for a particular calendar month to the extent that the Firm Order (a) does not exceed the amount of the binding Forecast for such calendar month by more than twenty percent (20%), and (b) requires delivery no less than ninety (90) days following the date on which CoreRx receives the Firm Order. CoreRx will not be in breach of this Section 5.4 if CoreRx's failure to supply Products is due to a Force Majeure event or if CoreRx's failure is limited to quantities in excess of the quantities specified in this Section 5.4; provided that CoreRx shall use Commercially Reasonable Efforts to Manufacture additional quantities of Product that exceed 120% of the binding forecast. CoreRx shall Deliver Product under each Firm Order no later than the Delivery Date specified in the applicable Firm Order; provided, however, that no Delivery of Product shall be

made more than two (2) Business Days in advance of the date specified for Delivery in a Firm Order without Bion's prior written approval. The Facility shall be indicated on documents accompanying each shipment of Product. In the event CoreRx will fail to meet a Delivery Date set forth in a Firm Order, CoreRx shall bear the incremental costs required for expedited transport above and beyond the cost incurred by the method outlined in the Delivery Terms.

**5.5 Cancellation or Deferral.** Bion may cancel or defer any Firm Order, in whole or in part, without penalty, provided that such cancellation or deferral notice is received by CoreRx 15 days prior to CoreRx's scheduled commencement of the manufacture of the Product under such Firm Order. If Bion cancels or defers a Firm Order, in whole or in part, with less than the aforementioned notice, CoreRx shall use its best efforts to minimize any charges to Bion

**5.6 Delivery.** CoreRx shall effect Delivery of each Firm Order in accordance with the Bion Intellectual Property, Applicable Laws (including cGMPs) and the Product Specifications (and for clarity, CoreRx shall only effect Delivery of Product pursuant to a Firm Order). CoreRx shall Deliver or arrange for Delivery of Product to the Delivery Address and in accordance with the Delivery Terms, in order to fill such Firm Order. Each container shall be marked as to the identity of the Product, the quantity of Product, the related Firm Order number, the related Bion product code and any other information required by the Firm Order. CoreRx shall bear all risk of loss or damage with respect to Product(s) until such Product(s) are Delivered to Bion. Each Delivery of Product shall be accompanied by a packing slip and a Material Safety Data Sheet for such Product. CoreRx shall also provide Bion with Agency certification, for those countries in which the applicable Agency is in the practice of requiring any such certifications.

**5.7 Transfer of Title.** Title to Product supplied hereunder shall pass to Bion contemporaneously with the transfer of risk of loss, as established by the Delivery Terms.

**5.8 Packaging.** All Product supplied hereunder shall be packaged in accordance with the Quality Agreement, and CoreRx shall ensure that such packaging is otherwise in accordance with the Bion Intellectual Property and Applicable Laws (including cGMPs), as well as the applicable Product Specifications. Without limiting the foregoing, all Product supplied hereunder shall also be labeled with a traceable batch number and the date of Manufacture. In addition, the packing slip shall contain gross, tare and net weights of the Product.

**5.9 Handling and Storage Prior to Delivery.** Prior to Delivery of Product to Bion, CoreRx shall handle and store all Product (including all Materials used in the Manufacture of such Product) in accordance with the Bion Intellectual Property and Applicable Laws (including cGMPs), as well as the applicable Product Specifications.

**5.10 Certificate of Analysis.** Prior to Delivery of Product CoreRx shall provide to Bion a certificate of analysis (COA) and a Certificate of Compliance (COC) for all manufacturing Batches. The COA shall contain the following information: (i) name, address, and contact phone number of the Facility where the Product was Manufactured, (ii) Product name, (iii) CoreRx batch number, (iv) date of Manufacture, (v) date of release, (vi) date of expiry, (vii) a list of each test performed, the acceptance limits as indicated in the Product Specifications, and the results obtained (and the COA should document actual values, where specifications are quantitative, and maintain the significant figures and rounding of numbers defined in the Product Specifications); and (viii) a release statement signed and dated by CoreRx indicating that the batch: (1) meets the Product Specifications; (2) was Manufactured in accordance with cGMPs, ANDAs, Applicable Laws, DMF (if applicable), the Bion Intellectual Property, and the controlled validated process; and (3) used only Materials that met their specifications. The COA should clearly state if reduced or skip lot testing is used to release the lot of Product provided to Bion. The CoreRx shall list only those process changes that required Bion review and approval in accordance with the Quality Agreement, manufacturing deviations (as defined in the Quality Agreement) and out of Product Specification (OOS) investigations applicable to the Product. In addition, a Certificate of Compliance shall be provided to Bion, which document shall be used to notify



Bion of any process changes, rework, reprocessing, significant manufacturing deviations, or OOS investigations associated with the Batch. CoreRx shall not Deliver Product unless and until such Product has been quality released by Bion based upon such COA. If quality control release of the Product is delayed for more than ninety (90) days due to an investigation, CoreRx will provide all necessary assistance to close any deviation in less than thirty (30) days thereafter.

**5.11 Supply Interruption.** If CoreRx is unable to supply any Product ordered by Bion in accordance with the terms of this Agreement, then CoreRx shall use Commercially Reasonable Efforts to remedy the problem or secure an alternative source of supply within a reasonable time at no cost to Bion, and any such alternative source of supply shall be on terms substantially identical with the terms of this Agreement. If CoreRx is unable to remedy the problem or secure an alternative source of supply within two (2) months after its initial failure to supply, then CoreRx shall consult with Bion and the parties shall work together to remedy the problem. If CoreRx is unable to remedy the supply problem after an aggregate period of three (3) months (or longer as agreed in writing by the Parties), commencing with the date upon which such failure to supply began, then Bion shall have the right (but not the obligation), to take the following actions with respect to the affected Product:

- (i) Bion may cancel any outstanding Firm Order for such Product, and Bion shall have no obligation to CoreRx for any Firm Order of the Product to the extent the Product has not been supplied as of the date of delivery of such cancelation notice; and/or
- (ii) if CoreRx is unable to the Product for a period exceeding one hundred and twenty (120) days from the confirmed delivery date on two consecutive occasions during any twelve (12) month period (“**Supply Interruption**”) then Bion may have the applicable Product manufactured by an Approved Manufacturer rather than by CoreRx. With respect to any Supply Interruption, CoreRx shall reimburse Bion within thirty (30) days of written demand for any actual cover costs paid by Bion to any customer of Bion or its Affiliates pursuant to Bion’s ordinary course contractual arrangement with such customer providing for payment to such customer in the event of a failure of supply of any Product by Bion or its Affiliates (“**Cover Costs**”), provided that Bion shall use Commercially Reasonable Efforts to mitigate such Cover Costs including by using any available safety stock and canceling orders promptly upon notice of a Supply Interruption.

**5.12 Business Failure.** If, from time to time during the Term, a Business Failure occurs, then Bion shall have the right (but not the obligation) to exercise the rights and remedies set forth in Section 5.12, and in connection therewith, the provisions set forth in Section 5.12 shall apply, mutatis mutandis.

**5.13 Subcontracting.** Prior to engaging a given Affiliate or Third Party subcontractor to perform any Manufacturing activities hereunder, CoreRx shall notify Bion thereof and discuss such subcontracting with Bion; provided that in all cases, CoreRx shall not subcontract any of its obligations hereunder, including any obligations to Manufacture any Product, to an Affiliate or Third Party without the prior written consent of Bion. With respect to any subcontracting (including to an Affiliate or a Third Party), CoreRx shall remain fully responsible and liable for all obligations hereunder, and fully guarantees and warrants the performance (in accordance with this Agreement) of any responsibilities so subcontracted, and assumes full vicarious liability for such activities performed by any subcontractor. Without limiting the foregoing, CoreRx shall cause any and all such subcontractors to comply with the applicable terms and conditions of this Agreement (including with respect to technology transfers (including as set forth in Section 5.14), intellectual property ownership provisions (including as set forth in Article 11) and any and all audit and inspection rights, including under Article 9). Any subcontracting of any Manufacturing or other activities hereunder shall be subject to the other applicable terms and conditions of this Agreement, in each case, to the extent applicable. Notwithstanding the foregoing, the use of a Third Party subcontractor shall not result in any increase in the Transfer Price, unless Bion expressly agrees in writing to an increase in the Transfer Price as a result thereof.

**5.14 Approved Manufacturer.** CoreRx shall, within thirty (30) days of Bion’s request at any time after a Product has received Regulatory Approval, assist Bion in the designation, qualification and

maintenance of Bion or its' designee as an alternative supplier of such Product (each, an "**Approved Manufacturer**") in the event of a Supply Interruption. Bion shall require any Approved Manufacturer to agree in writing to observe the terms of this Agreement relating to confidentiality and the manufacture of Products. CoreRx will (i) provide the Approved Manufacturer copies of the physical embodiment of all processes, protocols, procedures, methods, tests and other know-how, relating to the Manufacturing of such Product and (ii) make available to the Approved Manufacturer via telephone or email, on a mutually convenient timetable, reasonable technical assistance with respect to the Manufacture of Product(s). In addition, upon the request of Bion from time-to-time during the Term, CoreRx shall provide reasonable technical assistance to the Approved Manufacturer with respect to such Approved Manufacturer's receipt, adoption and establishment of the manufacturing process for the Product, including: (a) allowing representatives of Approved Manufacturer to observe the manufacturing process at the Facilities, on a mutually convenient timetable, in connection with such transfer, (b) supplying analytical test methods and other testing know-how including method validation reasonably required to perform release testing or other testing as may be required by the applicable Agency or other regulatory authority, and (c) providing Approved Manufacturer with appropriate quantities of reference standards and samples related to such Product in order to facilitate its testing. In addition, (i) Approved Manufacturer shall have the right to reference CoreRx's (and its Affiliates') regulatory filings and such other regulatory submissions controlled by CoreRx (or any its Affiliates) reasonably necessary for the manufacture of such Product, and CoreRx (and its Affiliates) shall grant, and hereby does grant, to Approved Manufacturer such right of reference and (ii) Approved Manufacturer shall have the right to use any know-how owned or otherwise controlled by CoreRx or any of its Affiliates to make, have made and use the Products.

**5.15 Samples.** Upon Bion's request, CoreRx will provide to Bion, at no additional cost, samples of Product from a Bion-specified Batch in quantities reasonably requested by Bion for inspection, testing and analysis. CoreRx will ship such samples as requested by Bion to a Bion designated address.

**5.16 Assistance with Regulatory Filings.** CoreRx shall be responsible for preparing documents to support ANDAs or other filing submissions for Products, as reasonably required by Bion, and shall provide a copy of such documents to Bion for review prior to submission to Agency by Bion. CoreRx shall continue to provide all such documents reasonably requested by Bion for maintenance of such ANDAs or other filing submissions. CoreRx shall continue to provide ongoing support reasonably requested by Bion for ANDA for each of the Products. CoreRx shall be responsible, at its cost, for receiving and maintaining any Facility licenses, authorizations, accreditations, permits and/or registrations granted or filed with an Agency, including those required for Manufacture of Products. CoreRx shall also provide Bion with Agency certification, for those countries in which the applicable Agency is in the practice of requiring any such certifications. For clarity, Bion shall be permitted to share information provided by CoreRx under this Section 5.16 with Affiliates and Third Parties (including sublicensees and Agencies) and such Affiliates and Third Parties shall be entitled to use such information in support for Products. If any Products are to be filed by Bion, in its sole discretion, in another country, and Bion selects to work with CoreRx in these countries, CoreRx will provide the support and cooperation for filing and work with Bion to get the Facility inspected and approved by the applicable country Agency, subject to mutually acceptable economic terms to be reached by the Parties.

**5.17 Product Supply.** CoreRx shall Manufacture and supply Products exclusively for Bion and not for any Third Party.

**5.18 Exclusivity.** Except as pursuant to this Agreement, neither Party nor their respective Affiliates shall for the duration of the Term of this Agreement develop or manufacture (including contract manufacturing) any other Drug Product for sale or distribution in the Territory that references the ANDA for the Reference Product or any foreign equivalent outside the Territory (regardless of whether such Product(s) are marketed under a generic, branded or private label) to any Third Party if either Party knows or has reason to know that such product will be sold or distributed in the Territory during the Term of this Agreement in the Territory. In providing or granting any rights to the Product outside the



Territory, the Parties shall obtain from each such grantee, licensee, beneficiary or acquiree (including Affiliates) of such rights their binding written agreement that they shall only sell and distribute the Product(s) within their specified territory, and not within any part of the Territory during the Term of this Agreement.

## ARTICLE 6. FINANCIAL PROVISIONS

**6.1** Except as explicitly provided in this Agreement, each Party shall be solely responsible for all costs and expenses associated with carrying out its responsibilities under this Agreement. The Product shall be manufactured at CoreRx's manufacturing facility that is FDA inspected and approved, and meeting all FDA requirements for manufacturing, pilot batches (engineering batches), exhibit (submission) batches, conduct stability studies and produce stability reports in form and substance capable of supporting FDA approval of the ANDA for the Product. For the sake of clarity, all costs for any external, out-of-pocket development costs including but not limited to: finished Product formulation development, finished Product analytical method transfer, project management, equipment qualification, engineering batch and registration batch engineering, pilot, pivotal or exhibit batches (excluding API required for such development batches) hereafter shall be borne by CoreRx.

**6.2 Transfer Price.** For each unit of Product ordered by Bion under Firm Orders hereunder and supplied by CoreRx to Bion in accordance with the terms and conditions of this Agreement, Bion shall pay CoreRx the Transfer Price, which payments shall be made in accordance with Section 6.8. The Transfer Price shall be established by mutual agreement of the Parties on an annual basis one (1) month prior to the commencement of Bion's next fiscal year, and once established shall remain in effect for the applicable fiscal year. When establishing the Transfer price for any fiscal year, the Parties shall each seek to identify opportunities to negotiate more favorable Materials prices. Notwithstanding the foregoing, the Transfer Price may be increased during a fiscal year if the cost of a Material increases by 10% of the cost for that Material upon which the most recent Transfer Price was based

**6.3 Productivity/Cost Improvements.** CoreRx agrees to use Commercially Reasonable Efforts to identify and implement all potential areas of cost improvement. At the request of Bion, appropriate representatives of Bion and CoreRx shall meet from time to time during the Term to discuss and agree on (a) objectives for a continuous improvement program, including cost improvements ("**Continuous Improvement Program**") and (b) the means of measuring and implementing the results of the Continuous Improvement Program. Progress against objectives shall be measured quarterly. CoreRx shall use all reasonable endeavors to achieve the agreed objectives and targets identified for the relevant period. The net benefits of cost reductions and improved efficiencies shall be shared equally by the Parties, including as reductions to the Transfer Price under this Agreement. In such case, the Parties shall reasonably discuss and agree on the amount of such reductions to the Transfer Price.

**6.4 Records.** Each Party shall keep and maintain or cause to be maintained books and records pertaining to its activities in connection with this Agreement.

**6.5 Reserved.**

**6.6 Invoicing, Payment and Taxes.** (a) Upon shipment of a Product to Bion, CoreRx shall submit invoices therefor to Bion. Bion shall pay each invoice within sixty (60) days from the date the Product arrives at Bion's designated port. All payments under this Agreement shall be made in U.S. Dollars.

(b) CoreRx shall be liable for all income and other taxes (including interest) (“**Taxes**”) imposed upon any payments made by Bion to CoreRx under this Agreement.

## **ARTICLE 7. QUALITY**

**7.1 Compliance and Investigation.** CoreRx shall Manufacture and supply Product in accordance with the Quality Agreement, the Product Specifications and Applicable Laws (including cGMPs) and strictly in accordance with the Bion Intellectual Property and any applicable DMF. CoreRx shall notify Bion immediately of any difficulty in Manufacturing Product in accordance with all of the terms and conditions of this Agreement. Bion may, at its option, investigate the cause of any failure, or require CoreRx to do so and provide Bion with a written report summarizing the results of CoreRx’s investigation. CoreRx shall complete any quality investigation within the number of days established in the Quality Agreement.

**7.2 Audits and Inspection of Facility.** From time to time as requested by Bion, CoreRx shall permit one or more qualified technical specialists from Bion (or its designee), upon reasonable prior notice and during normal business hours, to conduct audits (including quality, safety and environmental) and other inspections of the Facility or any other facility which is proposed to be used to Manufacture Product, provided such audits shall not last more than five (5) days per site (or such longer period of time as Bion (or its designee) may reasonably require to conduct such audit or inspection). Bion shall not be obligated to pay CoreRx for such visits, but Bion shall be solely responsible for its out-of-pocket costs to conduct such site visits. Observations and conclusions of Bion’s audits and inspections will be issued to CoreRx. CoreRx shall provide a written response within fifteen (15) Business Days of receipt of such observations and conclusions. The Parties will discuss such response and promptly agree on corrective action to be implemented. The agreed corrective action shall be implemented by CoreRx, at CoreRx’s expense. If reasonably necessary (as determined by Bion), Bion shall have the right, at CoreRx’s expense, to direct any actions with respect to implementation of corrective action with the assistance of CoreRx in order to ensure that any such corrective actions are appropriately completed. Bion may, in its sole discretion, suspend any Firm Orders until the agreed corrective action has been fully implemented. Bion shall have the right to review all relevant documentation.

**7.3 Quality Control Tests.** CoreRx shall perform, at its quality control laboratories, such quality control tests as are indicated in the Bion Intellectual Property and the Product Specifications, in accordance with the test methods and procedures described by Bion. The final release of each Batch of Product shall be done by Bion following the process specified in the Quality Agreement, and the procedures to be followed in the event of a Batch failure are specified in the Quality Agreement. Core Rx shall be responsible for any Batch failure unless the failure is not associated with any testing Manufacturing or packaging process carried out by CoreRx as provided in this Agreement.

**7.4 Production Batch Failure.** Should any production Batch fail to meet the quality control Specifications, or be produced in a manner not corresponding to the Bion Intellectual Property or Bion-approved Manufacturing documents or not in accordance with Applicable Laws (including cGMPs), CoreRx shall immediately notify Bion. Such Batch shall not be Delivered hereunder.

**7.5 Retention Samples.** CoreRx is responsible for maintaining, retaining and storing retention samples sufficient to perform full specification analyses, which storing and testing are as indicated in the Bion Intellectual Property and/or the Specifications, as applicable. Such amounts shall be retained for the longer of (i) the expiration period of the Product plus one (1) year or (ii) such longer period of time as may be required by the Applicable Law.

**7.6 Notification of Agency Action.** Each Party shall immediately notify the other Party of any information such Party receives regarding any threatened or pending action by any Agency that has the potential to impact any Product supplied to Bion hereunder, including any Agency non-approval or regulatory action. Upon receipt of any such information, the Parties shall consult in an effort to arrive

at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing contained herein shall be construed as restricting the right of either Party to make a timely report of such matter to any Agency or take other action that it deems to be appropriate or required by Applicable Law.

**7.7 Safety or Efficacy Claims.** Each Party shall immediately notify the other Party of any information of which it is aware concerning Product supplied to Bion which may affect the safety or efficacy claims or the continued marketing of the Product. Any such notification will include all related information in detail. Upon receipt of any such information, the Parties shall consult in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing contained herein shall be construed as restricting the right of either Party to make a timely report of such matter to any Agency or take other action that it deems to be appropriate or required by Applicable Law. Each Party will notify the other immediately of any health hazards with respect to Product which may impact employees involved in the Manufacturing of Product.

**7.8 Complaints.** Each Party shall immediately notify the other Party of any complaints received by such Party concerning a Product supplied hereunder. CoreRx shall investigate complaints as requested by Bion and shall take corrective action to avoid future occurrences.

**7.9 Agency Inspection.** CoreRx hereby agrees to notify Bion in writing immediately of any proposed visit or inspection by any governmental authority, including, any Agency (such as the FDA, DEA, etc.) or any environmental regulatory authority if such visit or inspection has the potential to impact Product, and agrees to permit one qualified representative of Bion to be present on site if requested by Bion. CoreRx hereby agrees to advise Bion, without undue delay, after the commencement of any unannounced visit or inspection relating to the Facility or the Manufacture of Products by any governmental authority (even if such visit constitutes a pre-approval inspection or similar review), including any Agency or any environmental regulatory authority, and agrees to permit one or more qualified representative(s) of Bion to be present on site for the portion of the audit affecting Product if requested by Bion. If Bion is not present during such proposed or unannounced visit or inspection, CoreRx shall provide brief daily summary reports during the course of the inspection to the extent the inspection relates to the Manufacture of Products. CoreRx shall promptly provide a written summary report of the results of the inspection to Bion in English to the extent the inspection relates to the Manufacture of Products. CoreRx shall promptly (and in no event later than one (1) Business Day) furnish Bion summaries of all observations, notes, reports, documents or correspondence with respect to any Agency requests or inspections of the Facility related to the Manufacture of Products, as well as a copy of each such observation, notes, report, document or correspondence and any proposed corrective actions, responses and other changes arising out of such review or inspection by such Agency. To the extent any of the Agency observations or requests relate to the Facility or the Manufacture of Products, CoreRx shall fully cooperate with Bion and take into consideration any of Bion's inputs, suggestions and other corrective measures to address any of such Agency's concerns and permit one or more qualified representative(s) of Bion to observe and assist CoreRx in responding to such Agency's observations. CoreRx shall fully apprise Bion of any corrective measures effectuated as a result of any inspection and permit one or more qualified representative(s) of Bion to ensure such corrective measures have adequately been implemented in accordance with the timelines and criteria and other commitments made by CoreRx to the Agency in question.

**7.10 Restricted Categories.** CoreRx hereby declares and covenants that as of the Effective Date of this Agreement it is not, and during the Term shall not, produce, package, label, warehouse, quality control test (including in-process, release and stability testing), release or ship any chemical entity classified as penicillin's, hormones, alkaloids, Beta-lactam antibiotics such as cephalosporin's, carbapenems or monobactams; sex hormones, cytotoxic or cytostatic anti-neoplastic agents; other highly active compounds; biological preparation containing live viruses or microorganisms; or other toxic,

non-drug substances or live agents “technical poisons” including pesticides, herbicides, fungicides, in the Facility.

**7.11 Labeling.** Bion may specify required labeling on Product and all components and containers. CoreRx will comply with all specified labeling as to each Product and each component and container and shall use only labeling which has been approved in writing by Bion in advance. CoreRx shall not use Bion labels on any products except Product for which such use has been approved by Bion. CoreRx shall not modify the Bion labels in any way without Bion’s prior written consent.

**7.12 Materials.** CoreRx shall maintain an adequate system, which functions as a risk-based assessment of its suppliers of Materials that are components of or may come in contact with the Product (such as primary packaging materials, excipients, and APIs). Furthermore, Bion may, at its option, independently conduct audits or participate in CoreRx audits (including quality, safety and environmental) of CoreRx’s suppliers of such Materials, on a routine or for-cause basis. As a result of such audits, if necessary, Bion shall have the right to direct CoreRx to disqualify a supplier as a source of Materials. CoreRx shall identify a new supplier as a source of Materials and replace the disqualified supplier with such new supplier, pursuant to the provisions set forth in Section 3.6. Notwithstanding the foregoing, CoreRx shall be fully responsible for sourcing and testing of Materials, qualification and management of its supplier(s) of Materials.

**7.13 Batch Records.** CoreRx shall provide Bion with all Batch records and any investigation or deviation reports related to Product for each Batch. Investigations into process deviations must be approved by Bion.

**7.14 Data Sets.** CoreRx will on an ongoing basis collect, graph, trend, and analyze data of and from the Manufacturing of each Batch of Product, and the accumulated data from all Batches of Product shall be the data set (“**Data Set**”). CoreRx will update the Data Set promptly following the Manufacture of each Batch of Product. The Data Set will include the following Manufacturing data for each Batch of Product, as may be modified by Bion from time to time: yield; cycle-time; lot numbers of Materials used; in-process testing results; Critical Process Parameters (or CPPs); Critical Quality Attributes (or CQAs); and Proactive Process Analysis (PPA). On or before the last day of each calendar month during the Term, CoreRx will update the Data Set (in graphical format, as appropriate) in writing to include each Batch of Product Manufactured during the month; complete review and approval of the Data Set by CoreRx management; and submit the approved Data Set in writing to Bion for review. The Parties acknowledge the Data Set will, among other things, provide the basis for ongoing process improvement and trend analysis. In the event that a deviation occurs during the Manufacturing of a Batch of Product, as part of the investigation of such deviation pursuant to Section 12.3, CoreRx will update the Data Set to include the data for such Batch within seven (7) calendar days of the occurrence or identification of such deviation, whichever is later; and CoreRx will generate run charts of data (from the updated Data Set) which include data from not less than ten (10) consecutive batches of Product Manufactured immediately preceding the deviation event to establish a baseline of Manufacturing performance against which the deviation Batch data may be compared. CoreRx shall be responsible for ensuring, verifying and delivering this Data Set.

**7.15 Quality Agreement.** The Parties shall negotiate in good faith and enter into a Quality Agreement with respect to the Manufacture of such Product within a reasonable time prior to the anticipated First Commercial Sale of the first Product. The Parties shall also negotiate in good faith and enter into a Safety data Exchange Agreement covering safety data exchange, adverse event reporting, patient support and management of patient compliance concerning the Products.

## ARTICLE 8. REGULATORY MATTERS

**8.1 Records.** CoreRx shall retain all records related to the (i) Manufacture of Product(s) for a period of not less than two (2) years from the expiration of the approved shelf life of the Product(s) to which said records pertain (or such longer period as required by Applicable Law) and (ii) Manufacture of Validation batches for five (5) years past the effective date of termination of this Agreement or two (2) years beyond the approved shelf life of the applicable Product(s), whichever is shorter (or such longer period as required by Applicable Law) (each such period shall be referred to as the “**Retention Period**”). CoreRx shall provide Bion with complete and accurate copies of the appropriate documents for each production Batch, upon Bion’s request. CoreRx shall, at the end of the Retention Period, either destroy the records or return the records to Bion at Bion’s written instructions.

**8.2 Audit Rights.** CoreRx’s Records shall be open to inspection and subject to audit and/or reproduction, during normal working hours, by Bion or its authorized representative (i) as required by governmental authorities or (ii) as may be desirable by Bion for any other valid business purpose. CoreRx shall preserve such Records for a period of ten (10) years after the end of the Term or for such longer period as may be required by Applicable Law. For the purpose of such audits, inspections, examinations and evaluations, Bion or its authorized representative shall have access to such records beginning on the Effective Date and continuing until ten (10) years after the satisfaction of CoreRx’s obligations under this Agreement. In addition, CoreRx shall provide adequate and appropriate workspace for Bion or its authorized representatives to conduct such audit. Bion or its authorized representative shall give CoreRx reasonable advance notice of an intent to audit.

**8.3 Subcontractors.** For clarity, CoreRx shall ensure that any subcontractor performing any Manufacturing activities complies with the foregoing provisions of Sections 8.1 and 8.2.

**8.4 Decisions on Recalls.** As between the Parties, Bion shall have the sole and absolute discretion as to whether to institute a recall or withdrawal Product (whether instituted at the request of an Agency or voluntarily instituted by Bion for any reason); provided that, to the extent practical, Bion shall notify CoreRx thereof prior to implementation. Notwithstanding anything to the contrary contained herein, CoreRx shall have no right to institute any recall or withdrawal of any Product. CoreRx agrees to abide by all decisions of Bion to recall or withdraw Product.

**8.5 Recalls.** In the event that Product(s) are recalled or withdrawn, CoreRx shall fully cooperate with Bion in connection with such recall or withdrawal. If such recall or withdrawal is caused by Product that contains a Deficiency or by CoreRx’s negligence or breach of this Agreement, CoreRx shall reimburse Bion for (i) all costs associated with the manufacturing of the recalled or withdrawn Product, including the Transfer Price for Product and other formulation, packaging and distribution expenses of Product (and including materials used in connection therewith), and (ii) all expenses incurred in connection with such recall or withdrawal.

**8.6 Marketing Authorizations.** As between the Parties, Bion (or its designee) shall have the sole right to prepare and file ANDAs for the Products with the applicable governmental authorities. Without limiting CoreRx’s obligations under Section 5.16, CoreRx shall provide Bion with such information and assistance as Bion may reasonably request for purposes of applying for and maintaining any ANDAs for Product including providing Bion with all reports, authorizations, certificates, methodologies, specifications and other documentation in the possession or under the control of CoreRx (or any of its Affiliates) relating to the Manufacture of Product or any component thereof for such filings.

**8.7 DMFs.** Without limiting CoreRx’s obligations under Section 5.16, CoreRx shall provide Bion with such information and assistance as Bion may reasonably request for purposes of applying for and maintaining any DMFs, as applicable, for Product Manufactured and supplied under this Agreement.



**8.8 Disclosure of Audits.** CoreRx acknowledges that governmental authorities (including Agencies) may, in conducting an inspection of Bion, request copies of reports of Bion audits of its suppliers. For clarity, in response to such a request, Bion may provide to the governmental authority (including any Agency) the report of any compliance audit conducted in accordance with this Agreement or the Quality Agreement.

## **ARTICLE 9. COMMERCIALIZATION**

**9.1 Marketing, Sales and Distribution Obligations.** Bion shall be responsible for all decisions regarding Commercialization of the Product or Products.

**9.2 Commercialization Outside the Territory.** For the avoidance of doubt, it is understood and agreed that Bion, as the holder of the ANDA for each Product shall have the right to commercialize any Product that has received final Regulatory Approval for sale in the Territory in countries that are outside the Territory, provided that If Bion requests that CoreRx provide a technology transfer for the production of the applicable Product outside the Territory for Commercialization outside the Territory, then CoreRx shall receive a technology transfer payment from the new manufacturer or the entity marketing the Product in the new countries.

## **ARTICLE 10. INTELLECTUAL PROPERTY**

**10.1 Bion Intellectual Property.** As between the Parties, Bion shall own all right, title and interest in and to the Bion Intellectual Property (including any and all information and data contained therein), and CoreRx is not acquiring any ownership interest in any Bion Intellectual Property (including any and all information and data contained therein) hereunder.

**10.2 CoreRx Intellectual Property.** As between the Parties, CoreRx shall own all right, title and interest in and to the CoreRx Intellectual Property, and Bion is not acquiring any ownership interest in any CoreRx Intellectual Property hereunder. CoreRx agrees and acknowledges that no information, know-how, data or other intellectual property, other than the Bion Intellectual Property, shall be used by or on behalf of CoreRx in the Manufacture of Products hereunder. If CoreRx uses any CoreRx Intellectual Property in the Manufacture of any Product then Bion shall have a non-exclusive, perpetual, irrevocable, paid-up and royalty-free license, including the right to grant sublicenses, under such CoreRx Intellectual Property to the extent necessary or useful for Bion to Develop, Manufacture or Commercialize the applicable Product.

**10.3 Grant of License.** Bion hereby grants to CoreRx a non-exclusive license to use, the Bion Intellectual Property solely to Develop the Products in accordance with this Agreement and to Manufacture Products for Bion in accordance with this Agreement. Unless otherwise consented to by Bion in writing, (i) CoreRx shall not use the Bion Intellectual Property (or any Specifications or any DMF) for any purpose other than the the Manufacture of Products for Bion hereunder and (ii) CoreRx shall not use any proprietary and/or confidential information or data of or provided by Bion or its Affiliates in the Manufacture of Product hereunder other than the Bion Intellectual Property.

**10.4 Improvements.** (a) Unless otherwise agreed in writing, all discoveries, improvements and/or inventions by CoreRx or any of its Affiliates, whether patentable or not, resulting from CoreRx's or its Affiliates' use of the Bion Intellectual Property or the Manufacture of Products shall be the sole and exclusive property of Bion ("**Bion Improvements**"), and shall be deemed to be Bion Confidential Information. For the avoidance of doubt, Bion Improvements shall automatically become part of Bion Intellectual Property and shall be subject to the license referenced in Section 10.3.

(b) Each Party shall promptly notify the other Party if it becomes aware of any Bion Improvement, and CoreRx shall reasonably assist Bion in protecting Bion's proprietary rights any Bion Improvement. CoreRx hereby represents and warrants to the Bion that all of its employees, officers, independent contractors, and agents who may perform activities under this Agreement have executed agreements (prior to performing any activities under this Agreement) requiring assignment to CoreRx of all



intellectual property made in performing activities under pursuant to this Agreement. CoreRx shall (at Bion's reasonable expense) take all reasonable additional actions and execute such agreements, instruments, and documents as may be reasonably required to perfect Bion's right, title, and interest in, to, and under Bion Improvements.

**10.5 IP Enforcement Matters.** If either Party learns of any actual or threatened infringement or misappropriation or any attack on the validity or enforceability by a Third Party with respect to Bion Intellectual Property anywhere in the Territory, such Party shall promptly notify the other Party and shall provide such other Party with available evidence of such events. Bion shall have the first option to pursue any enforcement or defense of Bion Intellectual Property against infringement or misappropriation, including defense against a declaratory judgment action alleging invalidity or non-infringement of any of the Bion Intellectual Property; provided, that Bion pays all costs and expenses related to the same, keeps CoreRx reasonably informed of its progress and provides CoreRx with copies of any substantive documents related to such proceedings and reasonable notice of all such proceedings. Any recovery of damages or other sums recovered in a proceeding or action covered by this Section 10.5 shall be applied first in satisfaction of any unreimbursed expenses and legal fees of Bion and next, if applicable, in satisfaction of the costs and expenses incurred by CoreRx in connection therewith, including reasonable attorneys' fees involved in the prosecution and/or defense of any proceeding or action and, if after such reimbursement any funds shall remain from such damages or other sums recovered, the remaining recovery shall be retained one hundred percent (100%) by Bion. In any infringement or misappropriation suit that Bion may institute to enforce Bion Intellectual Property, or in any declaratory judgment action alleging invalidity, non-infringement or non-misappropriation of any Bion Intellectual Property brought against CoreRx or Bion, the other Party shall, at the request and expense of the Party initiating or defending the suit or action, cooperate and assist in all reasonable respects, having its employees testify when requested and making available relevant records, papers, information, specimens and the like. In addition, upon the reasonable request of the Party instituting an action under this Section 10.5, or if required by Applicable Law, the other Party shall join such action and shall be represented using counsel of its own choice, at the requesting Party's expense; provided, that if Bion does not initiate an action hereunder on the advice of outside patent counsel, then CoreRx may not require Bion to join such action but CoreRx may have Bion join such action as an involuntary Party, but Bion shall not be required to participate in such action.

**10.6 IP Defense Matters.** If any notice of infringement or misappropriation is received by, or a suit is initiated against, Bion or CoreRx by a Third Party concerning the Manufacture, use, importation, offer for sale, or sale of a Product in the Territory, the Parties shall consult in good faith regarding the best response before either Party responds to the Third Party.

## ARTICLE 11. CONFIDENTIALITY AND PUBLIC DISCLOSURE

**11.1 Confidential Information.** (a) During the Term of this Agreement and for five (5) years thereafter without regard to the means of termination, each Party (i) shall maintain in confidence all Confidential Information of the other Party; (ii) shall not use such Confidential Information for any purpose except as permitted by this Agreement; and (iii) shall not disclose such Confidential Information to anyone other than those of its Affiliates, sublicensees, prospective sublicensees, employees, consultants, agents or subcontractors who are bound by written obligations of nondisclosure and non-use no less stringent than those set forth in this Article 11 and to whom such disclosure is necessary in connection with such Party's activities as contemplated in this Agreement. Each Party shall ensure that such Party's Affiliates, sublicensees, prospective sublicensees, employees, consultants, agents and subcontractors comply with these obligations. Each Party shall notify the other promptly on discovery of any unauthorized use or disclosure of the other's Confidential Information.

(b) Notwithstanding the provisions of Section 11.1(a), a receiving Party may disclose Confidential Information of the disclosing Party to the extent such disclosure is (i) made in response to a valid order

or subpoena of a court of competent jurisdiction or other governmental body of a country or any political subdivision thereof of competent jurisdiction; provided, that receiving Party provides the other Party with prior written notice of such disclosure (if practicable) in order to permit the other Party to seek a protective order or other confidential treatment of such Confidential Information; and provided further that any Confidential Information so disclosed will be limited to that information that is legally required to be disclosed in such response to such court or governmental order or subpoena; (ii) otherwise required by Applicable Laws; provided, that receiving Party provides the disclosing Party with prior written notice of such disclosure (if practicable) in order to permit the disclosing Party to seek a protective order or confidential treatment of such Confidential Information; and provided further that any Confidential Information so disclosed will be limited to that information that is legally required by Applicable Law to be disclosed; (iii) made by the receiving Party to a Regulatory Authority, as required to obtain or maintain Regulatory Approvals; provided that reasonable efforts shall be used to ensure confidential treatment of such Confidential Information; (iv) made by the receiving Party to a Third Party as may be necessary or useful in connection with the Commercialization of a Product (including the manufacture of a Product); provided the Third Party is bound by written confidentiality obligations no less protective than those set forth in this Agreement; (v) made by receiving Party to a U.S. or foreign tax authority to the extent legally required by Applicable Laws to be disclosed; (vi) made by receiving Party to its representatives or to Third Parties in connection with sublicensing or financing activities of the receiving Party; provided that the Third Party is bound by written confidentiality obligations no less protective than those set forth in this Agreement; (vii) made by receiving Party or any of its representatives in the filing or publication of Patent Rights relating to the Product to the extent such disclosure in the filing or publication of Patent Rights is reasonably necessary for support of the Patent Rights; (viii) made by receiving Party to comply with Applicable Laws related to securities laws disclosure requirements or any disclosure requirements of any applicable stock market or securities exchange; or (ix) made by receiving Party in compliance with Section 11.2.

**11.2 Press Releases and Public Announcements.** No public announcement or disclosure may be made by either Party with respect to the subject matter of this Agreement without the prior written consent of the other Party; provided, that the provisions of this Section 11.2 will not prohibit (a) any disclosure required by any applicable legal requirement, including any legal requirement or listing standard of any exchange or quotation system on which the disclosing Party's securities are listed or traded or to be listed or traded (in which case the disclosing Party will provide the other Party with the opportunity to review in advance the disclosure and to contest the same, including reasonable opportunity to seek a protective order or to seek confidential treatment of such disclosures under Rule 24b-2 of the Securities Exchange Act of 1934, as amended), (b) any disclosure made in connection with the enforcement of any right or remedy relating to this Agreement, (c) any disclosure made by Bion or CoreRx to their respective employees, collaborators, licensors, licensees, contract research organizations, business partners, investors, potential investors, lenders and potential lenders provided the person receiving the disclosure has undertaken a confidentiality obligation to Bion or CoreRx, as the case may be, substantially similar to the confidentiality obligations the Parties have undertaken to each other under this Agreement, or (d) any disclosure made pursuant to a press release in a form mutually agreed to by the Parties (or any other subsequent disclosure containing substantially similar information).

## **ARTICLE 12. REPRESENTATIONS AND WARRANTIES**

**12.1 General Representations and Warranties.** Each of Bion and CoreRx represents, warrants, covenants and agrees that, at all times during the Term, (a) it is a corporation duly organized and validly existing and in good standing under the laws of its jurisdiction of organization, (b) it is qualified or licensed to do business and in good standing in every jurisdiction where such qualification or licensing is required, (c) it has the corporate power and authority to execute, deliver and perform its obligations under this Agreement, and the execution, delivery and performance of this Agreement by it has been duly authorized by all necessary corporate action, (d) this Agreement has been duly executed and

delivered by it, and (e) this Agreement constitutes the valid and binding obligations of it, enforceable against it in accordance with its terms except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting creditor's rights generally, or general principles of equity.

**12.2 Representations, Warranties and Covenants for Product.** CoreRx represents, warrants and covenants that all Product shall, at the time of Delivery, (a) be Manufactured in accordance with, and shall meet, the Product Specifications, (b) be Manufactured in accordance with all Applicable Laws (including cGMPs) in effect on the day of Delivery, (c) be Manufactured in accordance with any applicable DMF, (d) be Manufactured in accordance with the Bion Intellectual Property (unless otherwise agreed by the Parties writing or in accordance with the Quality Agreement), (e) not be adulterated or misbranded within the meaning of the U.S. Federal Food, Drug and Cosmetic Act (the “Act”), or any similar Applicable Law of any other jurisdiction, (f) not be an article that may not, under the provisions of the Act, or any similar Applicable Law of any other jurisdiction, be introduced into stream of commerce, and (g) have at least the Minimum Remaining Percentage of its maximum shelf-life, as evidenced by expiry dating, remaining.

**12.3 Inspection.** Bion (or its agent) shall inspect at Bion's discretion (based minimally on physical inspection, identity test and review of the certificate of analysis provided by CoreRx pursuant to Section 5.10) the Product following Delivery for variances and defects. If Bion claims that a shipment of Product did not, at the time of Delivery, meet the representations, warranties or covenants specified in Section 12.2 or the quality requirements set forth in Article 8 (a “Deficiency”), Bion shall notify CoreRx based on the foregoing inspection within [ninety (90)] days after receipt of such Product at Bion's (or its designee's) site, which notice shall provide the quantities affected, the basis for the claim and other information reasonably necessary for CoreRx to assess the claim. Notwithstanding the foregoing, if Bion claims that the Deficiency is a Latent Defect, Bion shall have the obligation to provide such notification to CoreRx in writing within ninety (90) days after Bion's discovery of such Latent Defect (or within ninety (90) days after Bion is notified in writing by a Third Party of such Latent Defect, if later). If Bion and CoreRx are unable to agree as to whether such Product contains a Deficiency, the Parties shall cooperate to have the Products in dispute analyzed by an independent testing laboratory of recognized repute selected by Bion and approved by CoreRx, which approval shall not be unreasonably withheld. The results of such laboratory testing shall be final and binding on the Parties on the issue of whether such Product contains a Deficiency. Such testing shall be for the determination of financial liability only and shall not determine releasability of Product. If the Products are determined to not contain a Deficiency, then Bion shall bear the cost of the independent laboratory testing and pay the Transfer Price with respect to the Products in accordance with this Agreement. If the Products are determined to contain a Deficiency, then CoreRx shall bear the cost of laboratory testing, and CoreRx shall, at Bion's election, either replace the rejected Products within [thirty (30)] days of the date of such determination, at no cost to Bion, or refund to Bion the Transfer Price paid for such Products plus any applicable delivery charge.

**12.4 Return or Destruction.** Any Product that is determined to contain a Deficiency and that is in Bion's possession shall, at Bion's option, either be returned to CoreRx or destroyed in accordance with Applicable Laws, in each case, at CoreRx's expense.

**12.5 Manufacturing Process and Validation.** CoreRx represents, warrants and covenants to Bion that (i) the Manufacturing process and test methods for Product (including all future process changes or test method changes prepared in connection with the Manufacture of Product) shall be validated prior to the filling of any Firm Orders; provided, however, that Bion may, in its sole discretion, accept Product from CoreRx prior to the completion of such validation and (ii) the Manufacturing process and test methods (and any change in the Manufacturing process or test methods) for Product shall, in each case, comply with the Applicable Laws (including cGMPs), and any such changes thereto shall be made in accordance with Sections 3.5-3.7 (to the extent applicable) and the Process Change Policy as specified in the Quality Agreement.

**12.6 Encumbrances.** CoreRx represents, warrants and covenants that, save for security interests expressly given in favor of Bion or its Affiliates, it will have good and marketable title, free and clear of any pledge, lien, restriction, claim, charge, security interest and/or other encumbrance, to all Product to be Delivered hereunder, and all Product supplied to Bion shall be free and clear of all pledges, liens, restrictions, claims, charges, security interests and/or other encumbrances at the time of Delivery.

**12.7 Employee Matters.** CoreRx represents, warrants and covenants that it shall comply with all rules and obligations vis-à-vis employees and self-employed consultants (if any), used in the Manufacture of Product or otherwise at the Facility, and, as set out by the Applicable Laws, collective and individual agreements, including (a) payment of salaries, social security charges, insurances and withholding taxes on the income received by the workers involved in the performance of this Agreement, as well as (b) any other obligations deriving from the employment agreement and/or self-employment agreement, including provisions protection of the personnel, safety and physical integrity, in full compliance with the Applicable Laws and the individual and collective agreements. CoreRx expressly undertakes to perform this Agreement using only personnel duly employed in accordance with the Applicable Laws.

**12.8 DISCLAIMER.** EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT, ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED.

### ARTICLE 13. INDEMNIFICATION

**13.1 Bion Indemnification.** Bion shall protect, defend, indemnify, and hold harmless CoreRx, its Affiliates and its and their respective officers, directors, employees, and agents, and their respective successors and permitted assigns (“**CoreRx Parties**”) from and against any and all Losses from Third Party Claims to the extent occurring, growing out of, incident to, or resulting directly or indirectly from: (a) a claim by a Third Party that the use of the Bion Intellectual Property by CoreRx (as directed by Bion) to Manufacture Product for Bion hereunder infringes the intellectual property rights of such Third Party; or (b) the sale of a Product by Bion but only in the event such Product was Manufactured by CoreRx in strict accordance with the Product Specifications and otherwise in accordance with the terms and conditions of this Agreement; except in each case to the extent CoreRx is obligated to indemnify Bion pursuant to Section 13.2.

**13.2 CoreRx Indemnification.** CoreRx shall protect, defend, indemnify, and hold harmless Bion, its Affiliates and its and their respective officers, directors, employees, and agents, and their respective successors and permitted assigns (“**Bion Parties**”) from and against any and all Losses from Third Party Claims occurring, growing out of, incident to, or resulting directly or indirectly from: (a) the failure of Product provided by CoreRx hereunder to meet the representations, warranties or covenants set forth in Section 12.2 ; (b) a breach by CoreRx of any of its representations, warranties, covenants, agreements or obligations under this Agreement (including any Addenda) or the Quality Agreement; (c) the negligence, recklessness or willful misconduct of CoreRx in Manufacturing Product or in the performance of its other obligations under this Agreement (including any Addenda) or the Quality Agreement; (d) a Manufacturing Infringement Claim; (e) the acts or omissions of CoreRx, its employees, agents or subcontractors in using the CoreRx Equipment in the Manufacturing of Product, or (f) any breach of the obligations undertaken by CoreRx vis-à-vis its personnel and self-employed consultants, including the obligations regarding salary, social security insurances and taxes.

**13.3 Indemnification Procedures.** The indemnified Party shall give the indemnifying Party CoreRx (a) prompt written notice of any claims made for which the indemnified Party knows or reasonably should know the indemnifying Party may be liable under the foregoing indemnification and (b) the opportunity to defend, negotiate, and settle such claims. Notwithstanding the foregoing, the failure to give such written notice will not affect the indemnification provided hereunder except to the extent the indemnifying Party shall have been actually prejudiced as a result of such failure. The indemnified



Party shall provide the indemnifying Party with all reasonable information in its possession, and all reasonable authority and all assistance, reasonably necessary to enable the indemnifying Party to carry on the defense of such suit; provided, however, that the indemnified Party reserves the right to retain its own counsel at its own expense to defend itself in such suit

**13.4 Settlement.** The indemnified Party shall not be responsible to or bound by any settlement made by the indemnifying Party without the indemnified Party's prior written consent, and the indemnifying Party shall not agree to or enter into any settlement without the indemnified Party's prior written consent; provided, however, that the indemnifying Party shall not be required to obtain such consent if the settlement involves only the payment of money and will not result in the indemnified Party becoming subject to injunctive or other similar type of relief and provided that such settlement does not require an admission by the indemnified Party and includes an unconditional release of the indemnified Party from all liability on claims that are the subject matter of such proceeding

**13.5 Limitation of Liability.** Except for breach of confidentiality obligations under Article 12 AND EXCEPT AS OTHERWISE PROVIDED IN SECTIONS 13.1-13.2, WITH RESPECT TO THIRD PARTY CLAIMS, IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES OR ITS OR THEIR RESPECTIVE OFFICERS, DIRECTORS, EMPLOYEES OR AGENTS BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES OR ITS OR THEIR RESPECTIVE OFFICERS, DIRECTORS, EMPLOYEES OR AGENTS FOR ANY PUNITIVE, INDIRECT OR CONSEQUENTIAL DAMAGES OR INDIRECT OR CONSEQUENTIAL LOSSES OF ANY KIND, NATURE OR DESCRIPTION WHATSOEVER (INCLUDING ECONOMIC LOSSES OR LOST PROFITS) SUFFERED OR INCURRED BY SUCH PARTY ARISING UNDER OR IN CONNECTION WITH THIS AGREEMENT OR AS A RESULT OF ANY ACTIVITIES HEREUNDER, REGARDLESS OF WHETHER ARISING FROM BREACH OF CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY IS ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE OR IF SUCH LOSS OR DAMAGE COULD HAVE BEEN REASONABLY FORESEEN.

**13.6 Insurance.** Not later than thirty (30) days before the date of the First Commercial Sale of any Product, Bion will, at its expense, and CoreRx will, at its expense, obtain and maintain in full force and effect, comprehensive general liability insurance, including product liability insurance with a minimum coverage of \$2,000,000 per occurrence (or claim) and \$5,000,000 in the aggregate limit of liability per year. Each Party shall have included the other Party as an additional insured to such Party's insurance policy. Upon a Party's reasonable request, the other Party hereto shall provide the requesting Party with certified copies of all applicable endorsements and certificates of insurance, both evidencing such coverage, which shall also state that a minimum of thirty (30) calendar days prior written notice of any proposed cancellation, or expiration without renewal, and five (5) Business Days' prior written notice of any proposed change in carriers or material terms of coverage. If the above policies are reported on a "claims made basis" then the applicable Party shall provide coverage five (5) years after the Agreement has terminated. For clarity, the foregoing insurance requirements shall not in any way limit either Party's liability with respect to its indemnification or other obligations under this Agreement.

#### ARTICLE 14. TERM AND TERMINATION

**14.1 Term.** This Agreement shall commence on the Effective Date and shall continue in full force and effect for a period of five (5) years from the commercialization of the last Product, unless earlier terminated pursuant to this Article 14 or mutually terminated by the Parties in writing (such period of time as this Agreement is in effect, the "**Term**"). At the request of Bion during the Term, the Parties shall negotiate in good faith a renewal of this Agreement in whole or on a Product-by-Product basis; provided, however, that as part of such negotiations, either Party may propose alternative terms, including alternative financial terms, which may apply during any such renewal period. For clarity, (i) neither Party shall have any obligation to renew this Agreement unless and until agreed to by such Party, and (ii) unless otherwise expressly agreed to by the Parties in writing, any new or different terms which are negotiated as part of the renewal, if any, shall only apply during the renewal period and shall

not in any way alter the terms of this Agreement during the initial Term.

**14.2 Breach.** If either Party shall materially breach this Agreement (or a given Addendum to the extent that the material breach relates solely to such Addendum or the Product thereunder), the non-breaching Party may give written notice to the other Party, specifying the nature of the material breach and, if such material breach is not remedied within thirty (30) calendar days of receipt of such notice (provided, however, that the cure period shall be suspended during any time that a Party seeks resolution of a dispute as to whether an alleged material breach occurred pursuant to any dispute resolution mechanisms under this Agreement), then the non-breaching Party shall have the right, in its sole discretion, immediately to terminate this Agreement upon written notice to the breaching Party. Notwithstanding the foregoing, if such material breach relates only to a given Product, then the non-breaching Party shall only have the right to terminate the applicable Addendum to which such material breach relates and this Agreement, and all other Addenda shall not be affected by such termination.

**14.3 Bankruptcy.** This Agreement may be terminated by written notice given by a Party upon the occurrence of any of the following with respect to the other Party: (a) such other Party becomes insolvent, or (b) voluntary or involuntary proceedings by or against such other Party are instituted in bankruptcy or under any insolvency law, which proceedings, if involuntary, shall not have been dismissed within ninety (90) days after the date of filing, or (c) a receiver or custodian is appointed for such other Party, or proceedings are instituted by or against such other Party for corporate reorganization or the dissolution of such other Party, which proceedings, if involuntary, shall not have been dismissed within ninety (90) days after the date of filing, or (d) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors, or substantially all of the assets of such other Party are seized or attached and not released within ninety (90) days thereafter.

**14.4 Study Failure.** In the event that any required or agreed study(ies) for a Product, including, without limitation, Bio-Equivalence Studies, fail more than two (2) times, Bion may terminate this Agreement with respect to the applicable Product upon ten (10) Business Days' notice to CoreRx.

**14.5 Termination for Refusal to File.** In the event that FDA issues a "Refusal To File" for a Product Regulatory Approval application because of a deficiency arising out of the dossier provided by CoreRx for the preparation of such application for Regulatory Approval, Bion shall reasonably work together in good faith with CoreRx and provide CoreRx one-hundred and eighty (180) calendar days to cure such problem so that Bion may re-file an application for Regulatory Approval that addresses the reasons for the refusal to file. In the event that a second refusal to file is received, or Bion believes in good faith, after reasonable consultation with CoreRx after the aforementioned one hundred eighty (180) calendar days allowed to resolve the problems associated with the "Refusal To File", that it is commercially unreasonable to re-file, Bion may terminate this Agreement with respect to the applicable Product upon thirty (30) calendar days' notice to CoreRx.

**14.6 Termination for Efficacy Study Requirement.** If applicable and in the event that FDA determines that the formulation of a Product shall not be eligible for final Regulatory Approval in the absence of efficacy or clinical studies, then Bion may terminate this Agreement with respect to the applicable Product upon sixty (60) calendar days' notice to CoreRx. Such termination shall be deemed an expiration of this Agreement with respect to the applicable Product pursuant to Section 14.1 and neither Party shall be deemed to have breached this Agreement as a result of such determination by FDA or to have any liability at law or equity to the other as a result of such termination.

**14.7 Termination for Supply Interruption.** Bion may terminate this Agreement pursuant to a Supply Interruption pursuant to Section 5.11.

**14.8 Termination for Force Majeure.** Bion may terminate this Agreement in the event of a Force Majeure that lasts for more than one hundred twenty (120) days with notice to CoreRx.

**14.9 Termination for Government or Legal Action.** Bion may terminate this Agreement with notice to CoreRx if (i) a permanent injunction is issued by a court of competent jurisdiction enjoining Bion's



sale of a Product; or (ii) sale of a Product has been enjoined or is the subject of active litigation that claims that the Manufacture or sale of the Product infringes a Third Party Patent Rights or market exclusivity rights.

**14.10 Consequences of Expiration or Termination.**

14.10.1 In the event that this Agreement is terminated in accordance with Sections 14.2 or 14.7, Bion shall have the right (but not the obligation) to (a) keep any or all outstanding Firm Orders in place, in which case CoreRx shall Manufacture and Deliver, in accordance with this Agreement, all quantities of Products ordered pursuant to such Firm Orders (regardless of whether the Delivery Date for such Products is before or after such termination) and Bion shall pay the Transfer Price with respect to such Products which meet the representations, warranties and covenants set forth in this Agreement or (b) cancel any or all outstanding Firm Orders, and with respect to any such cancelled Firm Orders, Bion shall have no further liability with respect thereto; provided that Bion shall only have the right to cancel Firm Orders pursuant to this clause (b) if this Agreement is terminated by Bion pursuant to Section 14.2 or Section 14.7.

14.10.2 Reserved.

14.10.3 Upon the expiration or termination of this Agreement, CoreRx shall assist Bion in effecting a smooth transition to an alternate supplier(s) for the manufacture of Products. Without limiting the generality of the foregoing, at the request of Bion, CoreRx shall support the technical transfer of the Manufacture of the Product to an alternate source(s) (including as set forth in Section 2.10).

14.10.4 Upon expiration or termination of this Agreement (or a given Addendum, as applicable), Bion and CoreRx shall immediately settle all outstanding invoices and other monies owed to the other pursuant to this Agreement (or such Addendum, as applicable). The termination or expiration of this Agreement (or a given Addendum, as applicable) shall not affect the rights and obligations of the Parties accruing prior to such termination or expiration. Subject to the foregoing, expiration or termination of this Agreement (or a given Addendum, as applicable) shall relieve and release all Parties from any liabilities and obligations under this Agreement (or such Addendum, as applicable), other than those specifically set forth in this Section 14.10 and those that survive termination in accordance with Section 14.12.

14.10.5 If this Agreement is terminated by Bion in accordance with Section 14.3 or Section 14.7, then the Parties agree to implement a transition plan, and to negotiate in good faith to allow Bion to lease the equipment, space, and personnel used to manufacture the Products pursuant to this Agreement, or acquire the Facility, equipment, and personnel used to manufacture the Products pursuant to this Agreement from CoreRx, provided such lease or acquisition will be structured in a manner that does not adversely impact another CoreRx customer then using another portion of the Facility for the production of products at the time of termination.

14.10.6 In the event that this Agreement is terminated in its entirety, then all Addenda then in effect shall automatically terminate as of the date of termination of this Agreement.

**14.11 Termination of Individual Addendum.** In the event that only a given Addendum expires or is terminated, as applicable, then the foregoing provisions of this Article 14 shall only apply to such Addendum and the Product thereunder.

**14.12 Survival.** In the event of a termination or expiration of this Agreement, only the following provisions shall survive termination or expiration: Articles 1, 10 (to the extent applicable), 11, and 13, and Sections 6.5-6.7, 7.5-7.6, 7.9, 8.1-8.2, 8.8, 12.8, 16.1-16.6, 16.8 and 16.10-16.12.

**ARTICLE 15. COMPANY EVENTS**

**15.1 CoreRx Company Event.** If CoreRx determines to commence the process for the sale of CoreRx, then CoreRx shall, within seven (7) days of the Board of Director's determination to commence such sale process, provide a written notice to Bion, setting forth the intent of CoreRx to

commence a sale process and written assurances that CoreRx will continue to comply with the terms of this Agreement.

**15.2 Assignment.** This Agreement shall be binding upon and inure to the benefit of each of the Parties hereto and their respective successors and approved assigns, provided, however, that CoreRx may not assign or transfer this Agreement whether by operation of law or otherwise without the prior written consent of Bion (which shall not be unreasonably withheld, conditioned or delayed). Each Party may assign this Agreement or grant a security interest in this Agreement as collateral security for purposes of obtaining financing or to any Party's lenders as collateral security. Subject to compliance with Section 15.1, no consent shall be required for a Party to assign this Agreement or transfer this Agreement by operation of law is in connection with a merger or acquisition or sale of all or substantially all of the assets of the assigning Party or to assign this Agreement to an Affiliate (provided, however, in the case of CoreRx, such Affiliate must be able to discharge its obligations under this Agreement including the various Addendums and CoreRx shall continue to remain responsible for the acts or omissions of such Affiliate). This Agreement shall be binding upon and shall inure to the benefit of the Parties and their successors and permitted assigns. Any assignment or transfer in contravention of this Agreement shall be null and void.

## ARTICLE 16. MISCELLANEOUS

**16.1 Interpretation and Construction.** Unless the context of this Agreement otherwise requires, (i) the terms "include," "includes," or "including" shall be deemed to be followed by the words "without limitation" unless otherwise indicated; (ii) words using the singular or plural number also include the other; (iii) the terms "hereof," "herein," "hereby," and derivative or similar words refer to this entire Agreement; (iv) the terms "Article," "Section" and "Attachment" refer to the specified Article, Section and Attachment of this Agreement, and (v) words of any gender include each other gender. Whenever this Agreement refers to a number of days, unless otherwise specified, such number shall refer to calendar days. The headings and paragraph captions in this Agreement are for reference and convenience purposes only and shall not affect the meaning or interpretation of this Agreement. This Agreement shall not be interpreted or constructed in favor of or against either Party because of its effort in preparing it.

**16.2 Independent Contractor Status.** The Parties shall at all times act as and be deemed to be independent contractors. Nothing in this Agreement shall be construed to render either Party as the agent, partner, joint venturer or employee of the other Party for any purpose whatsoever, and neither Party shall have any authority to enter into any contracts (other than settlement agreements pursuant to the applicable provisions of this Agreement) or assume any obligations for the other Party nor make any warranties or representations on behalf of that other Party.

**16.3 Waiver.** The waiver by either Party of a breach of any provision contained herein shall only be effective if in writing and shall in no way be construed as a waiver of any succeeding breach of such provision or obligation or the waiver of the provision or obligation itself.

**16.4 Severability.** If any provision of this Agreement shall be held illegal or unenforceable, that provision shall be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect and enforceable.

**16.5 Further Assurances.** Each Party hereto agrees to execute, acknowledge and deliver such further instruments and documents, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of this Agreement

**16.6 Notices.** Any notice or other communication to be given under this Agreement by any Party to any other Party shall be in writing and shall be either (a) personally delivered, (b) mailed by registered or certified mail, postage prepaid with return receipt requested, (c) delivered by reputable overnight express delivery service or same-day local courier service, (d) delivered by confirmed (or answered back) telex or facsimile transmission, to the address of the applicable Party as set forth below, or to

such other address as may be designated by the Parties from time to time in accordance with this Section 16.6. Notices delivered personally, by overnight express delivery service or by local courier service shall be deemed given as of actual receipt. Mailed notices shall be deemed given ten (10) Business Days after mailing and five (5) Business Days after expedited mailing services. Notices delivered by telex or facsimile transmission shall be deemed given upon receipt by the sender of the answerback (in the case of a telex) or transmission confirmation (in the case of a facsimile transmission); provided, however, that telex or facsimile that is sent after 5:00 pm (recipient's local time) shall be deemed given at 9:00 am (recipient's local time) on the next Business Day.

If to Bion at: Bionpharma Inc.  
600 Alexander Road, Suite 2-4B  
Princeton, NJ 08540  
Telecopier: (609) 380-3311  
With a copy by email to [admin@bionpharma.com](mailto:admin@bionpharma.com)

If to CoreRx at: CoreRx Inc.  
14205 Myerlake Circle  
Clearwater, FL 33760  
Telecopier: (727) 259-6971  
With a copy by email to [todd.daviau@corerxpharma.com](mailto:todd.daviau@corerxpharma.com).

or to such other address as each Party may designate for itself by like written notice.

**16.7 Dispute Resolution.** The Parties shall initially attempt in good faith to resolve any significant controversy, claim, allegation of breach or dispute arising out of or relating to this Agreement (hereinafter collectively referred to as a “**Dispute**”) through negotiations between senior executives of Bion and CoreRx. If the Dispute is not resolved within thirty (30) calendar days (or such other period of time mutually agreed upon by the Parties) of notice of the Dispute, then the Parties agree to submit the Dispute to non-binding mediation in an attempt to resolve the Dispute. Unless otherwise mutually agreed by the Parties, only if the Dispute is not resolved through negotiations or non-binding mediation as set forth herein, may a Party resort to litigation.

**16.8 Governing Law, Jurisdiction and Waiver of Jury Trial.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York. The United Nations Convention on International Sales of Goods shall not apply to the transactions contemplated by this Agreement. The Parties irrevocably agree that the State and Federal Courts located in the State, City, and County of Southern District of New York, shall have exclusive jurisdiction to deal with any disputes arising out of or in connection with this Agreement and that venue is proper in such Courts, and each Party irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the courts of the Southern District of New York and agrees not to bring any claim regarding such a dispute in any other court, and to waive unconditionally any objection to the laying of venue in such forum, including any claim of inconvenient forum. Each Party hereby expressly consents and submits to the personal jurisdiction of the Federal and State Courts in the State and County of the Southern District of New York. EACH PARTY HERETO WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY SUIT, ACTION OR OTHER PROCEEDING ARISING OUT OF THIS AGREEMENT.

**16.9 Force Majeure.** A Party shall not be liable for nonperformance or delay in performance, except for defaulted obligations of payment, to the extent that such nonperformance or delay in performance is not due to its negligence and is caused by any event reasonably beyond the control of such Party, including wars, hostilities, revolutions, riots, civil commotion, national emergency, strikes, lockouts, unavailability of supplies, epidemics, fire, flood, earthquake, force of nature, explosion, terrorist act,

embargo, or any other Act of God, (each a “**Force Majeure Event**”). In the event of any such delay, the delayed Party may defer its performance for a period equal to the time of such delay, provided that the delayed Party gives the other Party written notice thereof promptly and, in any event, within thirty (30) calendar days of discovery thereof, and uses its good faith efforts to cure the excused breach. In the event of a Force Majeure that lasts for more than one hundred twenty (120) days, then Bion shall have the right upon written notice to CoreRx to terminate this Agreement or any one or more Addenda in accordance with Section 14.8.

**16.10 Entire Agreement; Amendments.** This Agreement and any Attachments and Schedules attached hereto, constitute the entire agreement between CoreRx and Bion with respect to the Products in the Territory and supersede all prior representations, understandings and agreements with respect to such Products, including the Confidentiality Agreement effective October 16, 2014 between the Parties. Furthermore, this Agreement shall supersede any and all pre-printed terms on any orders, invoices, and other related documents and any and all orders issued by CoreRx. This Agreement may only be amended by a statement in writing to that effect signed by duly authorized representatives of Bion and CoreRx. The intent of this Agreement is to include items necessary for the proper execution and completion of the performance under this Agreement. The documents comprised by this Agreement are complementary, and what is required by any one shall be as binding as if required by all. Words and abbreviations that have known or technical trade meanings are used in this Agreement in accordance with such recognized meanings. In the event of a conflict or inconsistency between this Agreement and any exhibit, schedule and attachments, the terms and conditions of this Agreement shall prevail.

**16.11 Counterparts.** This Agreement may be executed in one or more counterparts, including by transmission of facsimile or PDF copies of signature pages, each of which shall for all purposes be deemed to be an original and all of which together shall constitute one instrument.

**16.12 Third Party Beneficiaries.** No term or provision of this Agreement is intended to be, or shall be, for the benefit of a sub-contractor, supplier, any individual member of the control group utilized for the bioequivalence studies, firm, organization, or corporation not a party hereto, and no such other Person, firm, organization or corporation shall have any right or cause of action hereunder.

**16.13 Use of Affiliates.** Bion shall have the right to exercise its rights and perform its obligations under this Agreement either itself or through any of its Affiliates, provided that Bion shall remain solely responsible for the acts, omissions and performance of such Affiliate as if such acts, omissions and performance had been provided by Bion itself under this Agreement. In addition, in each case where a Party’s Affiliate has an obligation pursuant to this Agreement or performs an obligation pursuant to this Agreement (to the extent permitted hereunder), (i) such Party shall cause and compel such Affiliate to perform such obligation and comply with the terms of this Agreement and (ii) any breach of the terms or conditions of this Agreement by such Affiliate shall be deemed a breach by such Party of such terms or conditions.

*[Remainder of this page intentionally left blank signature page follows]*

**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be duly authorized, executed, and delivered this Agreement intending it to take effect as of the Effective Date.

**CORERX INC.**



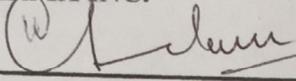
Name:

Title: President and Chief Executive Officer



**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be duly authorized, executed, and delivered this Agreement in tending it to take effect as of the Effective Date.

**BIONPHARMA INC.**

  
11/24/2020

Name: Venkat Krishnan

Title: President and Chief Executive Officer



**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be duly authorized, executed, and delivered this Agreement in tending it to take effect as of the Effective Date.

**BIONPHARMA INC.**

---

Name: Venkat Krishnan

Title: President and Chief Executive Officer

**ATTACHMENT 1**  
**PRODUCTS**

**Table 1. Identification of Reference Product**

<b>Product</b>	<b>API</b>	<b>Dosage Form; Route</b>	<b>Strengths</b>	<b>Proprietary Name</b>
Enalapril Solution	Enalapril Powder for Oral Solution	Solution	1mg/mL	Epaned®

ATTACHMENT 2 has been intentionally omitted.

**Exhibit 1 to Addendum Product Specifications**

(See Attached)

**[Attach Specifications as Exhibit 1]**

**Exhibit 2 to Addendum Certain Bion Intellectual  
Property**

(See Attached)

**[List relevant Bion Intellectual Property on this Exhibit 2]**